MAZIE SLATER KATZ & FREEMAN, LLC
COUNSELLORS AT LAW
103 Eisenhower Parkway
Roseland, NJ 07068
(973) 228-9898
Fax (973) 228-0303
www.mazieslater.com

David A. Mazie*
Adam M. Slater*°
Eric D. Katz*°
David M. Freeman
Beth G. Baldinger
Matthew R. Mendelsohn°

Karen G. Kelsen°
Cheryll A. Calderon
David M. Estes
Adam M. Epstein°
Michael R. Griffith°
Matthew Tonzola
Christopher J. Geddis

*Certified by the Supreme Court of New Jersey as a Civil Trial Attorney

°Member of N.J. & N.Y. Bars

January 27, 2020

VIA EMAIL
Honorable Joel Schneider
United States Magistrate Judge
U.S. District Court - District of New Jersey
Mitchell S. Cohen Building & US Courthouse
1 John F. Gerry Plaza, Courtroom 3C
4th and Cooper Streets
Camden, New Jersey 08101

Re: IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION
Civil No. 19-2875 (RBK/JS)

Dear Judge Schneider:

Please accept this letter on behalf of the Plaintiffs, addressing the agenda issues in advance of the January 28, 2020, Case Management Conference ("CMC").

1. Expansion of the MDL

The parties have discussed the issues posed by the expansion of the MDL to encompass losartan and irbesartan claims. At this point, Plaintiffs are prioritizing issues to be addressed, in large part based on the Court's guidance during the January 15, 2020, Case Management Conference (hereafter "January 15 CMC"). Plaintiffs have targeted (i) expansion of the PSC through formation of additional PSC committees, and (ii) initial pleading issues – which include

the entry of an amended direct filing order (see below), and (iii) preparation of master complaints (once the additions to the leadership structure are finalized). Plaintiffs expect that the proposed additions to the leadership structure will be finalized within one week at the latest and can be promptly submitted to the Court for approval.

In discussions with the defense it appears that there is consensus that the pace of the valsartan cases should not be impacted by the expansion of the MDL. This will allow the valsartan cases to continue to proceed without interruption, and allow the losartan and irbesartan cases to develop and proceed at a reasonable pace, utilizing the pleading forms and other groundwork already in place from the work performed in connection with valsartan. Defendants have identified a handful of potentially differentiating issues, including additional defendants, variation in manufacturing processes, variation in the quantity of or percentage of contaminated pills, variation in the contamination levels, and potentially others, which the parties should ultimately meet and confer on as those cases are structured.

2. Direct Filing Order

Plaintiffs have been advised that there are defendants who are apparently new to the litigation who have not agreed to entry of a direct filing order, which the Court clearly has the authority to enter. This is puzzling to the plaintiffs since the order on file with the Court preserves and does not impact defenses, and simply provides for an efficient administrative mechanism to enable cases to be filed directly into the MDL, avoiding the need for cases to be filed elsewhere and then be transferred to the MDL. Plaintiffs are hopeful that this can be easily resolved. A meet and confer on January 27, 2020 seemed to resolve the issues as Plaintiffs agreed to unequivocal

language, and to place on the record our stipulation that the entry of this order will only be an administrative vehicle and will not impact substantive rights.

3. Legacy Pharmaceuticals Motion to Dismiss

Plaintiffs believe that this motion should be denied without prejudice or held in abeyance as the parties and the Court address more pressing issues. If and when this motion proceeds, Plaintiffs will seek jurisdictional discovery, especially in light of Plaintiffs' understanding that Legacy obtained the pills at issue through wholesalers located in New Jersey.

4. Downstream Defendant Discovery

a. Wholesalers

Plaintiffs met and conferred with counsel for one of the Wholesaler Defendants on December 24, 2019, and attended a second meet and confer scheduled by Wholesaler Defendants on January 8, 2020 which was for the most part postponed due to a scheduling conflict for one of the defense attorneys.

In lieu of the January 8, 2020 meet and confer, Wholesalers instead sent their own proposed Requests for Production to be served by Plaintiffs upon Wholesalers, and later that evening, inexplicably served a lengthy memorandum addressing Wholesalers' discovery requests as to class Plaintiffs, beyond the PFSs previously approved by the Court which had not been previously discussed.

A third meet and confer was scheduled on January 17, 2020 with various Wholesaler Defendants, during which Plaintiffs attempted to identify specific categories of discovery that the Wholesaler Defendants would be willing to answer, and the parties ultimately agreed that Plaintiffs would send a revised set of discovery to the Wholesaler Defendants. Plaintiffs did so and asked

Defendants to meet and confer on January 24, 2020. Defendants advised that they still objected to the format of the Plaintiffs' proposed discovery requests. Plaintiffs then served a further revised, narrowed set of document requests, and renewed the request to meet and confer to attempt to resolve any remaining open issues prior to the CMC. A copy of the proposed requests for documents to the wholesaler/distributor defendants is attached hereto as Exhibit 7. As the Court has made clear, further requests will be permitted at a later date as needed.

Plaintiffs have also served a streamlined DFS on the wholesalers/distributors and are prepared to meet and confer or discuss during the conference. A copy of the proposed DFS to the wholesaler/distributor defendants is attached hereto as Exhibit 7.

b. Retailers

Since the last conference with the Court, Plaintiffs have worked with counsel representing the retailer Defendants. Plaintiffs sent a revised set of discovery to Defense counsel on January 22, 2020 and invited counsel to a meet and confer. Defense counsel indicated that more time would be needed. Consistent with what was served on the wholesaler/distributor defendants, Plaintiffs sent a revised set of narrowed document requests to the retailers and requested the scheduling of a meet and confer to try to resolve any remaining open issues prior to the January 28, 2020 conference. A copy of the proposed requests for documents to the retailer defendants is attached hereto as Exhibit 8. As the Court has made clear, further requests will be permitted at a later date as needed.

Plaintiffs have also served a streamlined DFS on the retailers/dispensers and are prepared to meet and confer or discuss during the conference. A copy of the proposed DFS to the retailers/dispensers is attached hereto as Exhibit 8.

5. Defendant Fact Sheet for Manufacturers

The Parties had a meet and confer on Monday January 27, 2020 regarding the Defendant Fact Sheets for Manufacturers (Plaintiffs have prepared a separate DFS for the API Manufacturers, and a separate DFS for the Finished Dose Manufacturers). Plaintiffs maintain that the narrow form of DFS is not duplicative since it focuses on what pills were taken by a particular plaintiff, and intended for the manufacturers will provide absolutely necessary information to ensure that there are no open questions on either side as to product identification and related narrow issues on a case specific basis. To the extent the manufacturers say they need information from the retailers in a particular plaintiff's cases in order to respond, that information can be provided once the retailers respond – remember it was the defense who objected to a single DFS that would have been answered in phases to address this exact issue. It is critical that there is written confirmation as to which pills, at what contamination levels, were taken by specific plaintiffs and this cannot be left to the plaintiffs to independently determine where definitive identification will be a significant component to answering numerous substantive questions on a case by case basis, and as a foundation to the expert reports on both sides. The defense's plan, to leave this as an unresolved question of fact to be litigated through trial is the height of inefficiency. The only alternative is to allow Plaintiffs to depose corporate reps on product ID in each plaintiff's specific case, as Plaintiffs are clearly entitled to this discovery. A copy of the proposed DFS to the Manufacturer Defendants is attached as Exhibit 9.

6. Show Cause Process for Delinquent Plaintiffs

Defendants have begun the process of serving deficiency notices for allegedly delinquent Plaintiffs. Plaintiffs request, as a starting point in determining the ultimate process, that

Defendants meet and confer to identify which identified deficiencies would rise to the level of triggering a Plaintiff's inclusion on a show-cause list. For instance, a number of Defendants' first-round of purported "deficiencies" were largely ministerial or technology-related, which can be remedied easily through prompt, informal cooperation among all counsel.

7. Defendants' Leadership Structure

The Court recently directed the defendants to add executive committee members to represent the interests of the retailers/dispensers and the wholesalers/distributors. It appears that a retailer/dispenser representative has been functioning with defendants' leadership but not so for the wholesalers/distributors, though certain defense attorneys have been involved in calls with plaintiffs on behalf of those defendants. Plaintiffs request that these appointments be finalized. Recent meet and confer calls have involved a large number of defendants, larger numbers than need be involved in these discussions, and this is hampering our ability to achieve the level of candor and back and forth needed to cooperatively work through the meet and confer process to resolve the inevitable string of difficult issues we will be facing going forward. Related, our ability to reach prompt agreement, or to finalize discussions, has been slowed as we are told that with so many defendants it takes time to get buy in on issues that appointed leadership should be authorized to address. It would be helpful if the Court could reiterate the roles of the appointed leadership and the necessity that the parties be able to function in a cooperative, efficient manner, and that defense leadership be accorded the authority to reach resolution of issues during discussions.

8. Challenges to Confidentiality Designations

On January 24, 2020, Plaintiffs submitted exemplar documents for the Court's in camera review pursuant to the Court's direction during the January 15, 2020 conference, as well as the

confidential and highly confidential documents cited *infra* regarding Defendants' product preservation and ongoing compliance with Core Discovery. This was submitted pursuant to the discussion during the conference call, initiated by the Court, directing Plaintiffs to submit these documents. This was confirmed in the Court's January 16, 2020 Order: "ORDERED that plaintiffs' counsel is granted leave to file with the Court an application to strike defendants' Confidentiality designations." Defense counsel's response to the submission, criticizing this submission in the absence of a meet and confer, is contrary to the discussion during the conference and the language in the Order, which speaks to submission of the documents for in camera review without the need to further discuss. And this made sense, since the documents at issue are so clearly lacking in any justification for designation as confidential.

For example, many of these documents consist of communications with the FDA regarding the product recall. These ministerial and administrative communications do not qualify for protection under any of the categories permitting such designations, such as trade secrets or confidential information. Further undermining the use of confidentiality designations for recall related communications is the inconsistency in these designations, as some of these communications have been designated confidential, whereas others have not.

9. <u>Product Preservation</u>

After the January 15, 2020 conference, Plaintiffs continued their review of the recall documentation produced in core discovery to date to assist Plaintiffs (and the Court) in understanding the scope of the preservation issues related to the recalled product. [1] Unfortunately,

[1] This includes productions made on January 22, 2020, by Defendants ZHP, Aurobindo, Mylan and Teva.

the core discovery production of communications with the FDA regarding the recall (including productions made on January 22, 2020 after the conference) raised more questions than answers. Plaintiffs therefore requested that Defendants provide affirmative representations as to whether they had destroyed any recalled product, by January 27, 2020 so this information could be provided to the Court. *See* Ex. 1, Email re Aurobindo Pill Preservation.

A more detailed description of the status of each Defendant's recall and associated pill destruction is provided below. [2]

a. Defendant ZHP

On January 22, 2019, ZHP produced a new set of correspondence with the FDA regarding the product recall, with some of these communications dating as far back as July 2018, and ending as recently as January 14, 2019. These newly produced documents indicate an eagerness to destroy recalled pills as recently as November 19, 2019. *See* SOLCO00000578 (as discussed in Plaintiffs' *in camera* letter to the Court, this document is designated Confidential Information and cannot be attached to this letter). On November 20, 2019, the FDA approved destruction. *See* Ex. 2, SOLCO00000370. This destruction was scheduled for January 3, 2020. *See* SOLCO00000578 (as discussed in Plaintiffs' *in camera* letter to the Court, this document is designated Confidential Information and cannot be attached to this letter). Plaintiffs are consequently concerned that ZHP may have destroyed *all* recalled product in its possession, and potentially a *mere 20 days ago*. If

[2] However, it is important for Plaintiffs to note, in response to the Court's question during the recent conference call as to the extent of product that needs to be preserved, that at this point Plaintiffs cannot agree that the full inventory of recalled and potentially contaminated valsartan will not need to be preserved for the foreseeable future. Determination of the scope of what has been collected, including from what manufacturing periods, lots, batches, and other variables will impact this issue as we learn more going forward.

this is not the case, ZHP's proactive efforts to obtain approval for destruction while under litigation hold obligations, is of great concern.

As of the filing of this letter, Defendant ZHP has neither confirmed nor denied whether it has engaged in any pill destruction, or the timing and extent thereof.

b. Defendant Mylan

As of January 16, 2020, Mylan stated that it had 2,221,234 bottles of recalled product in its possession. *See* Ex. 3, MYLAN-MDL2875-00037464. Mylan also indicated that it would not request destruction, and instead "request product to be held in quarantine at Stericycle pending a legal hold due to on-going litigation." *Id.* However, Mylan only first indicated that it was quarantining product due to a legal hold on October 22, 2019. *See* Ex. 4, MYLAN-MDL2875-00037462.

Nevertheless, on January 27, Counsel for Mylan confirmed that Mylan has not destroyed any recalled product.

c. Defendant Teva

As of December 18, 2019, Teva indicated that it had initiated a legal hold on destroying recalled products. *See* TEVA-MDL2875-00014719 (as discussed in Plaintiffs' *in camera* letter to the Court, this document is designated Confidential Information and cannot be attached to this letter). However, this legal hold was only first conveyed to the FDA on August 8, 2019. *See* TEVA-MDL2875-00015129 (*id.*). Indeed, in the months prior to August 8, 2019, Teva repeatedly requested authorization to proceed with destruction. *See, e.g.,* TEVA-MDL2875-00014832 (January 4, 2019, email asking for authorization to destroy) (*id.*), TEVA-MDL2875-00014767 (March 30, 2019, email asking for authorization to destroy) (*id.*). On April 1, 2019, the FDA

provided Teva with approval to proceed with destruction. *See* TEVA-MDL2875-00014761 (*id.*). It is therefore unclear whether Teva engaged in any pill destruction prior to August 8, 2019.

As of the filing of this letter, Defendant Teva has neither confirmed nor denied whether it has engaged in any pill destruction.

d. Defendant Torrent

As of March 12, 2019, Torrent indicated that it had destroyed pills on *five separate occasions*. *See* TORRENT-MDL2875-00004222 (as discussed in Plaintiffs' *in camera* letter to the Court, this document is designated Restricted Confidential Information and cannot be attached to this letter). The correspondence with the FDA further indicated that destruction certificates were attached to a February 2019 update, but no such destruction certificates were produced with the February 2019 update in Torrent's core discovery production. As discussed *infra*, Torrent has likewise failed to produce subsequent monthly recall updates that were submitted to the FDA from April 2019 to present, so the full extent of Torrent's destruction remains unknown.

As of the filing of this letter, Defendant Torrent has not confirmed whether it has engaged in any subsequent pill destruction beyond the five instances of destruction previously reported to the FDA.

e. Defendant Hetero

As of July 12, 2019, Hetero indicated that it had received a large quantity of recalled product from consignees, in addition to a large quantity of recalled product located at Camber's New Jersey warehouse. *See* HETERO_USA000029541 (as discussed in Plaintiffs' *in camera* letter to the Court, this document is designated Confidential Information and cannot be attached to this letter). However, no documents produced in Core Discovery to date clarify whether any of

the bottles in Hetero's possession have been destroyed or are even being quarantined. No written approval from the FDA allowing for destruction has been produced in the core discovery production. Hetero has likewise failed to produce subsequent monthly recall updates that were submitted to the FDA from August 2019 to present.

As of the filing of this letter, Defendant Hetero has neither confirmed nor denied whether it has engaged in any pill destruction.

f. Defendant Aurobindo

On January 24, 2020, Counsel for Aurobindo confirmed that Aurobindo has not destroyed any of the recalled bottles in its possession. *See* Ex. 1.

g. Information Required for Identification of Destroyed Product

For the above Defendants who may have engaged in pill destruction, Plaintiffs further requested (and repeat here for the benefit of the Court) that those Defendants provide a date certain they would produce documents sufficient to show the following information required to assist Plaintiffs in making any determinations regarding the necessary scope of pill preservation:

- **Destroyed Product in Defendants' Possession, Custody and Control:** quantity, lot number, batch number, NDC code, expiration date, destruction date, and witnesses to that destruction.
- **Undestroyed Product in Defendants' Possession:** quantity, lot number, batch number, expiration date, and NDC code.
- **Outstanding Undestroyed Product Still in the Possession of Consignees (such as Defendants McKesson, Cardinal, and AmerisourceBergen, among others):** quantity, lot number, batch number, expiration date, and NDC code.

10. Core Discovery

a. Ongoing Correspondence with the FDA

Following the January 15, 2020 conference, Plaintiffs wrote to each Defendant regarding their ongoing compliance with the Court's Core Discovery order requiring production of communications with the FDA to be provided within 7 days. *See* Ex. 5, Pls' Email to ZHP as an example.

On January 22, 2020, Defendants ZHP, Mylan, and Aurobindo provided additional correspondence with the FDA. Defendant Teva confirmed there was no additional correspondence beyond one discrete email, which it produced. Minutes before the filing of this letter, Defendant Hetero, proffered an additional production of correspondence to the FDA. Torrent has not proffered any additional productions, but likewise did not offer any certification that their core discovery productions were up to date.

Despite these additional productions, Plaintiffs continue to have concerns that Defendants are not in compliance with the Core Discovery Order regarding correspondence with the FDA for at least two specific sets of communications: 1) communications with the FDA regarding the administration of the recall (and, by extension, associated product destruction), and 2) communications with the FDA by designated agents who have been given express approval to communicate with the FDA on behalf of defendants.

i. Recall and Pill Destruction Communications with the FDA

In ZHP's January 22, 2020, production of supplemental correspondence, ZHP produced some 220 documents consisting of communications with the FDA. Many of these documents relate to ZHP's destruction of recalled product, and date back to July 2018. Given the almost 2-

year timeframe, it defies logic that so few emails would have been exchanged with the FDA regarding the recall and the destruction of some one million bottles of material. Even more troubling, it appears as though Jun Du was communicating with the FDA on these recall issues with a personal gmail address (and not with a company serviced account). *See* SOLCO00000547 (as discussed in Plaintiffs' *in camera* letter to the Court, this document is designated Restricted Confidential Information and cannot be attached to this letter). It should be noted that, Mr. Du's frequent usage of his personal gmail address is in violation of an alleged corporate policy against using personal email or devices for work purposes. Plaintiffs request assurances that relevant documents including communications made to the FDA by Mr. Du using his personal gmail account are not only being collected and produced, but are also being appropriately preserved. This request likewise extends to any other similarly situated ZHP employees as well.

Additionally, Hetero and Torrent have completely failed to produce months-worth of FDA-mandated and required monthly recall updates. These recall updates include information regarding the quantity of product received, and destruction (if any). Plaintiffs request that the Court order Hetero and Torrent to produce these subsequent monthly recall updates, as well as certificates of destruction submitted to the FDA as part of these monthly recall updates, immediately.

ii. Third Party Designated Agents

As discussed during the January 15, 2020 conference, several (and possibly all) Defendants are communicating with the FDA about issues related to the nitrosamine contamination through third party designated agents. While some Defendants had previously produced a very limited set of correspondence from third parties and/or registered agents, Plaintiffs believe that other communications have occurred which have not been produced by Defendants. Additionally,

Plaintiffs have concerns about whether these registered agents are complying with the Court's preservation order.

For example, one consultant for Defendant ZHP emailed the Director of the Division of Drug Quality, Office of Manufacturing and Product Quality, and Center for Drug Evaluation and Research ***on his own, directly from his own personal comcast email address, without including any employees from ZHP***. *See* PRINSTON00073197 (as discussed in Plaintiffs' *in camera* letter to the Court, this document is designated Restricted Confidential Information and cannot be attached to this letter). It is unclear what efforts, if any, have been made to ensure that this consultant has been preserving all relevant documents and communications made from his personal email address, and/or created on his personal computer. Plaintiffs have reason to believe there may be dozens of other consultants used by Defendants creating electronically stored information (either in the form of emails or communications with the FDA, or electronic documents). [3] Plaintiffs must have clarity as to the full scope of the identity and role of all FDA designated agents.

As such, Plaintiffs request the identity of all third parties who have been appointed as designated agents for communications with the FDA on behalf of each Defendant. Plaintiffs additionally request that Defendants confirm, with Plaintiffs and the Court, that all ongoing correspondence and communications made by third parties has been, or will be, produced by

[3] These registered agents who have been given express approval to communicate on behalf of some Defendants with the FDA include manufacturing consultants, cGMP consultants, and possibly toxicologists. Several US law firms, including Duane Morris and Hogan Lovells likewise appear to be directly communicating with the FDA regarding issues related to the nitrosamine contamination on behalf of some Defendants.

Defendants pursuant to their obligations under the Core Discovery Order and the Court's January 17, 2020, Order.

b. Other Core Discovery Issues

The Court gave Defendants an extension until January 31, 2020 to produce the missing exhibits to EIRs, Form 483s, and other documents produced during core discovery. Plaintiffs were hopeful, given the Court's extension, that they would be receiving a rolling production, but to date, plaintiffs have not received any of those documents.

Plaintiffs have been contacted by Mylan informing them that Mylan will be requesting an extension for the production of attachments to the inspection reports of their three finished dose facilities. Mylan has represented that this production of attachments to finished dose facility inspection reports will be completed by February 28, 2020. Mylan further confirmed that it would still produce the attachments to the inspection reports for its API manufacturing facility (along with 483s, EIRs, and correspondence related to its finished dose manufacturing facilities) by the January 31st, deadline. Plaintiffs are agreeable to such an extension.

The Court further ordered defendants to produce unredacted versions of core discovery documents. Plaintiffs have so far received unredacted versions only from Aurobindo, Mylan and Hetero USA.

11. <u>ESI Update</u>

Plaintiffs have asked defendants for an update as to the status of their efforts to collect, search, and produce ESI now that the search terms procedure has been agreed to. The only Defendants plaintiffs have received responses from are Mylan and ZHP. Plaintiffs have met and conferred with Mylan regarding narrowing of a few search terms that have been determined by

Mylan to be creating large false-positives in their documents and continue to meet and confer to further narrow those specific terms for Mylan. Plaintiffs have met and conferred with ZHP regarding Chinese translations of search terms. ZHP provided plaintiffs with their proposed translations on January 13, 2020. The Court had provided Plaintiffs two weeks in which to respond, and Plaintiffs have already provided ZHP with their proposed edits to the search terms modifiers list and proposed edits to the primary search terms.

12. Status of Service on Hetero and Aurobindo

Plaintiffs have now perfected service pursuant to the Hague convention on Mylan Laboratories Limited (the Indian Mylan entity), and Hetero Drugs (the Indian Hetero entity). D.E. 343. Plaintiffs expect service on the Aurobindo entity in the coming weeks. *See* Ex. 6, Affidavit regarding status of service on Aurobindo.

Thank you for your courtesies and consideration.

Respectfully,

Adam M. Slater